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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,963	09/19/2000	Kevin W. Anderson	M 6560 OS/OAPT	5388

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COGNIS CORPORATION  
2500 RENAISSANCE BLVD., SUITE 200  
GULPH MILLS, PA 19406

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 06/03/2003

25

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/663,963

Applicant(s)

WENZEL ET AL.

Examiner

Dr. Kailash C. Srivastava

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on March 24, 2003 as Paper Number 24.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 4-5, 8-9 and 24-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 7 and 10-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

1. Applicants' Supplemental Appeal Brief filed March 24, 2003 as Paper Number 24 in response to Notification of Non-Compliance mailed February 27, 2003 as paper number 23 is acknowledged and entered.
2. Claims 1-28 are pending.
3. Claims 4-5, 8-9 and 14-28 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected claims, there being no allowable generic or linking claim.
4. Claims 1-3, 6-7 and 10-13 are the subject of Applicants' Supplemental Appeal Brief filed March 24, 2003 as Paper Number 24.
5. In view of the new prior art encountered during a search subsequent to applicants' filing of Supplemental Appeal Brief, Paper Number 24 cited *supra*, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below. To avoid abandonment of this application, applicants must follow one of the two following two options:

file a response under 37 CFR 1.111 (if this Office Action is non-final) or under 37 CFR 1.113 (if this action is final); or,

request reinstatement of the Supplemental Appeal Brief cited *supra*.

If reinstatement of the Supplemental Appeal Brief is requested, such request must be accompanied by another supplemental brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

6. Claims 1-3, 6-7 and 10-13 are examined on merits. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 U.S.C. § 112***

7. Claims 1-3, 6-7 and 10-12 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- The phrase, "Substantially free of particulate material and bacteria" in Claim 1(e) renders that claim unclear, confusing and indefinite. The phrase is indefinite

because the metes and bounds for the phrase, "Substantially free of particulate material and bacteria" are not defined in either the claims or the specification. The term, "substantially" does not clearly establish the amount or degree to which bacteria or particulates should be present in the source of biotin comprising said culture medium. Applicants are required to clearly state the amounts of particulate material or bacteria that should be absent from the source of biotin that comprises their culture medium.

All other claims depend directly from the rejected claim 1, and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

8. Applicant's arguments regarding the rejection to Claims 1-3, 6-7 and 10-12 under 35 U.S.C. §112, second paragraph on page 3 of the Office Action mailed 8/22/2002 (paper Number 21) have been fully considered but are not persuasive. Applicants, citing a number of case laws, argue that the phrase "substantially free of particulate material and bacteria" is sufficiently definite, as written, and satisfies all of the requirements under 35 U.S.C. §112, Second paragraph" (see, Arguments in Supplemental Appeal Brief, Page 2, Lines 20-22). Applicants further argue, "claim terminology is sufficiently definite under 35 U.S.C. §112, second paragraph, unless there is an unreasonable degree of uncertainty in view of the specification and the art as to what is being claimed" (Please see, arguments in Supplemental Appeal Brief, Page 2, Lines 23-25). On page 3, Lines 8-11 of arguments in Supplemental Appeal Brief, applicants further argue that "Based on the plain meaning of the words, in light of specification and what is known in art biotin should be substantially free of extraneous materials and contaminants as well as, bacteria".

In view of applicants' argument that one main element of applicants' patentable invention is that the source of biotin in claimed culture medium is "substantially free of particulate material and bacteria", applicants have burden to define the metes and bounds for the term "substantially free of particulate material and bacteria".

### ***Claim Rejections Under 35 U.S.C. § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

***A person shall be entitled to a patent unless –***

**(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

10. Claims 1-3, 6-7 and 12 are newly rejected under 35 U.S.C. §102(b) as anticipated by Wickerham (J. Bacteriology, 1946, Volume 52, Pages 293-301).

Claims recite a culture medium comprising a carbon and energy source (e.g., glucose), a source of inorganic nitrogen (e.g., ammonium sulfate), potassium phosphate, calcium, biotin free of particulate matter and bacteria, and a trace metal.

Wickerham discloses a culture medium comprising: glucose, ammonium sulfate, biotin, potassium phosphate, calcium chloride, sodium chloride, copper, iron, zinc and other trace elements (Page 294, Lines 32-39 and Page 295, Lines 2-11). This medium discloses an organic carbon/energy source (i.e., glucose), an inorganic nitrogen source (i.e., ammonium sulfate), a metal salt, potassium phosphate, biotin, an alkali metal (i.e., sodium), an alkaline earth metal (i.e., magnesium), transition metals (e.g., iron) trace metal (boron), and mixtures of those metals (See, Page 294, Lines 32-39 and Page 295, Lines 2-11). Please note that Wickerham used purified vitamins (e.g., biotin) bought from commercial sources, dissolved them in a buffer solution and filter sterilized the vitamin (e.g., biotin) solution. Thus, Wickerham's vitamin solution was free of particulate material and bacteria.

Therefore, the cited prior art reference anticipates the cited claims.

### ***Claim Rejections Under 35 U.S.C. § 103(a)***

11. Claims 1-3, 6-7 and 10-13 stand rejected under 35 U.S.C. § 103 (a) as obvious over Wickerham (J. Bacteriology, 1946, Volume 52, Pages 293-301) in view of Shirai et al (U.S. patent 5,618,708).

Claims recite a culture medium comprising a carbon and energy source (e.g., glucose), a source of inorganic nitrogen (e.g., ammonium sulfate), potassium phosphate, calcium, a trace metal, an antifoam agent, and a chelating agent and biotin that is free of particulate matter and bacteria.

Teachings from Wickerham have already been discussed *supra*. Wickerham teaches a culture medium comprised of all the ingredients that are disclosed in the culture medium in claimed invention except for an antifoam and a chelating agent.

Shirai et al., disclose a culture medium comprising citric acid, glucose, ammonium sulfate, biotin or a source of biotin, potassium phosphate, calcium chloride, sodium chloride, copper, iron, zinc and other trace elements and an antifoam agent (Column 5, Lines 65-68 and Column 6, Lines 1-32). Thus, Shirai et al. teach a culture medium comprising an organic carbon/energy source, an inorganic nitrogen source, a metal salt, potassium phosphate, a chelant (i.e., citric acid) a vitamin (biotin, or source thereof) and a trace metal or mixtures of trace metals (See, Column 5, Lines 65-68; Column 6, Lines 1, 8, 19-21 and 31; Column 7, Lines 30-35, 45-55, Tables 1-3 and 13). Shirai et al. also obtain biotin in the same manner as the applicants (See Specification, Page 14, Lines 21-23) because Shirai et al.'s culture medium also comprises either pure biotin (See, Tables 2, 3 and 13) or the source of biotin is yeast extract (See Table 1) or corn steep liquor (Column 6, Lines 20-21). Furthermore, Shirai et al. dissolved all the ingredients of their culture medium in water (Column 8, Lines 15-25, Table 3) and subsequently sterilized their fermentation medium at 110°C (Column 8, Lines 10-11). Thus, in the cited prior art reference, the sources for biotin are same as in the claimed invention and the prior art culture medium is also prepared according to the same steps as is recited in the claimed invention. Therefore, biotin in the prior art culture medium composition intrinsically must be "free of particulate materials and bacteria" as is claimed because prior art culture composition is also comprised of same ingredients and said culture medium is prepared according to the same steps as those recited in the claimed invention.

One having ordinary skill in the art would have been motivated to modify the teachings from Wickerham (Page 294, Lines 32-39 and Page 295, Lines 2-11) according to the teachings from Shirai et al. (Column 5, Lines 65-68; Column 6, Lines 1, 8, 19-21 and 31-32; Column 7, Lines 30-35, 45-55, Tables 1-3 and 13; Column 8, Lines 10-11 and 15-25, Table 3) to incorporate a chelating agent and an antifoam in their culture medium, because both Wickerham and Shirai et al. references teach a culture medium comprising an organic carbon/energy source, an inorganic nitrogen source, a metal salt, potassium phosphate, a vitamin (biotin, or source thereof) and a trace metal or mixtures of trace metals and Shirai et al. reference remedies the deficiency of antifoam and chelant components in Wickerham's culture medium and further teaches that in said culture medium the source for biotin is same and the culture medium is prepared in the same manner following same steps as claimed in the instant invention.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify teachings from Wickerham according to the teachings from Shirai et al. to obtain a culture medium comprising an organic carbon/energy source, an inorganic nitrogen source, a metal salt, potassium phosphate, a chelant (i.e., citric acid) a vitamin (biotin, or source thereof) and a trace metal or mixtures of trace metals, wherein source of vitamin is either pure vitamin obtained from a commercial source or corn steep liquor or yeast extract.

None of the prior art references cited above teach the proportions of different components of culture medium to be the same as claimed in the instant invention. However, the adjustment of particular conventional working conditions (e.g., proportions/ratios of different components in a composition, temperature, pH and mode of sterilization etc.) is deemed merely a matter of judicious selection and routine optimization of a result effective variable, which is well within the purview of the skilled artisan.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. Applicants' arguments in the arguments section of Supplemental Appeal Brief cited *supra* regarding rejections to Claims 1-3, 6-7 and 12 under 35 U.S.C. §103(a) have been fully considered but are not persuasive. Applicants argue that "teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants' disclosure. Applicants further argue that "Nowhere within the four corners of the Shirai reference is it either taught or suggested to employ" a biotin component that is free of particulate material and bacteria. As discussed *supra* applicants have obtained biotin for their culture medium either in the pure form from a commercial source or from same crude sources (i.e., corn steep liquor or yeast extract) as are cited in the cited Shirai et al. prior art reference. Thus, within the four corners of Shirai et al. reference it is intrinsic that the biotin in Shirai et al's culture medium is "substantially free of particulate matter and bacteria".


## CONCLUSION

13. No Claims are allowed.

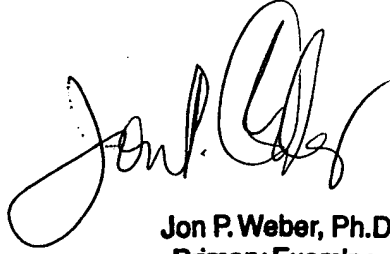
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday-Thursday from 7:30A.M. to 6:00 P. M. (Eastern Standard or Daylight Saving time).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Kailash C. Srivastava, Ph.D.  
Patent Examiner  
Art Unit 1651  
(703) 605-1196

May 30, 2003

  
Jon P. Weber, Ph.D.  
Primary Examiner

  
Michael G. Wityshyn  
Supervisory Patent Examiner  
Technology Center 1600